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a wrap adapted to be secured to said body surface, said wrap having substantially a laminar construction including several lamina providing an inner layer adapted to face said body surface when said wrap is so secured, and outer layer facing away from said body surface, and a plurality of individual lamina between said inner and outer layers, each said lamina being substantially coextensive in area throughout said laminar construction and formed of a material facilitating substantially an encircling movement when said wrap is secured to said body surface;

B10 at least one temperature sensor, each said temperature sensor mounted to said inner lamina to measure an actual temperature of said body surface;

at least one TE device, each said TE device mounted to said laminate at substantially a mid-laminate position and centrally within said coextensive area to selectively deliver one of a heating and cooling effect to said body surface; and

a control unit adapted to be connected to said wrap for receiving said actual temperature of said body surface from each said temperature sensor and for communication with each said TE device to operate the same providing one of said heating and cooling effect thereby achieving a desired temperature of said body surface.

REMARKS

The Office communication, dated February 11, 2003, mailed following a telephone interview on January 29, 2003 conducted with the examiner, John A. Jeffery, replaces the Office communication, dated September 11, 2002, and restarts the statutory period for response in connection with the examination of the invention in Therapeutic Apparatus disclosed and claimed in the above-identified application. The reason for the action on the part of the Patent and Trademark Office is discussed in an "Interview Summary" (PTO – 413), specifically the

additional comments set out in a continuation sheet attached to the Interview Summary, accompanying the Office communication to which attention is now directed.

The examiner indicated that applicant was not required to submit a separate record of the interview.

In an "Office Action Summary" the examiner indicated that claims 1 through 58 were presented in the application and subject to examination. The disposition of the claims is as follows: claims 1 through 23, 32 through 45 and 48 through 50 are rejected; claims 24 through 31, 46, 47 and 51 through 57 are objected to (the examiner, however, indicated that the claims under objection contain allowable subject matter, and that each claim would be allowed if the claim is rewritten in independent form including the limitations of the base claim and all intervening claims); and claim 58 is allowed.

Prospectively, however, the examiner indicated that claims 11 – 14 and 19 – 22 also contained allowable subject matter, and that these claims, also, would be allowed if applicant successfully overcame the rejection of claim 11 under 35 U.S.C. §112 ¶2 and presented claim 11 in independent form including the limitations of the base claim and each intervening claim.

Regarding "Drawings"

The Office communication addressed as a first substantive issue the drawing of the application, as filed. To this end, the examiner required submission of a copy of each figure including in red an enlarged legend and figure number. In addition, the examiner required the applicant to address Figs. 4A – 4E, each of which are objected to under Manual of Patent Examining Procedure, Section 608.02. The basis for the objection is that the figures lack proper cross-hatching of lamina of the wrap of the apparatus to indicate the material of construction.

As the examiner requested, applicant has addressed this substantive issue of objection in a separate letter addressed to the examiner, yet accompanying this amendment.

Regarding “Claim Objections”

Claims 3 and 4 were objected to by the examiner because of the presentation in each claim of the word “devise” rather than “device.” Both claims 3 and 4 have been canceled so that the ground of objection should be withdrawn.

Regarding “Claim Rejections – 35 U.S.C. § 112”

Claim 10 has been amended to recite with greater specificity the lamina of the wrap of the therapeutic apparatus, and to locate the lamina within the wrap. Particularly, the lamina heretofore recited as “upper layer” is now recited as “outer layer” and the lamina of concern, heretofore recited as “layer,” is now recited as “inner layer.” This wording is consistent with the discussion of the particular lamina set out in the written description.

Accordingly, the rejection of claim 10 under 35 U.S.C. §112 as being indefinite should be withdrawn. Claim 11 was rejected on the same ground and similarly amended. Accordingly, the rejection of claim 10 and 11 should be withdrawn.

Favorable reconsideration of the rejection of claims 10 and 11 under 35 U.S.C. § 112 is requested.

Regarding claims reciting “Allowable Subject Matter”

Claim 11 now appears as new claim 59, a claim that includes the limitations of base claim 1 and intervening claims 8 and 10. It is respectfully submitted that claim 59, as rewritten, is not subject to the rejection advanced against the predecessor claim, and since it is properly rewritten should be indicated as allowable over the prior art of record.

Favorable reconsideration and allowance of claim 59 and dependent claims 12 through 14

and 19 through 22 is requested.

Rewritten claim 59 and dependent claims 12, 13 and 19 through 22 have been amended in minor fashion to better and more consistently define features of the wrap of the apparatus. It is respectfully submitted, however, that no amendment should dissuade the examiner from indicating the allowance of the claims.

Claims 24 through 31, 46, 47 and 51 through 57 were also indicated as including allowable subject matter. Again, allowance of the claims was indicated contingent on rewriting several of the claims in independent form to include the limitations of the base claim and any intervening claims.

Claims 24 and 26 now appear as new claims 60 and 61, respectively. Both claims 60 and 61 are dependent on claim 12. Claim 60, however, further includes the recitation and location within the wrap of the apparatus of a wiring/tubing layer, and further defines the connection and positioning of the TE device and each temperature sensor, respectively. Claim 61 also includes further recitation and location of the wiring/tubing layer, a connection to the TE device, and recites that the inner layer comprises a fluid transfer medium and each temperature sensor is mounted to the fluid transfer medium.

Claim 27 now appears as new claim 62, also a dependent claim directly dependent on claim 61. Claim 62 recites that the wrap of the apparatus further comprises a layer providing at least one expandable cavity for filling with fluid, as well as a location disposed between the wiring/tubing layer and one or the other of the first and second insulate layers.

While claims 24, 26 and 27 are not written in independent form as suggested by the examiner, it is nevertheless respectfully submitted that claims 60 through 62 because of their specific dependency are the equivalent of a series of new independent claims.

Accordingly, it is respectfully submitted that claims 60 through 62, together with dependent claims 25, 28 through 31, 48 and 49 are allowable. We look forward to favorable reconsideration of each claim and an indication that the claims are allowed.

Claims 46, 47, 51 and 53 have been rewritten as new claims 63 through 66, respectively. Each claim includes the limitations of claim 33 and intervening claim 42. In addition, claim 63 includes the limitation of claim 46, claim 64 includes the limitation of claim 47, claim 65 includes the limitations of claims 48 and 51, and claim 66 includes the limitations of claims 49 and 53, respectively.

It is submitted that claims 63 through 66, together with dependent claims 52 and 54 through 57 are also allowable. Accordingly, the examiner now should also indicated the formal allowance of these claims. Favorable reconsideration is requested.

Finally, claim 67 dependent on claim 13 is also considered allowable. Applicant awaits an indication of the examiner's action toward that end, as well.

Regarding "Claim Rejections – 35 U.S.C. § 102"

Claims 1, 7 – 9 and 23 were rejected under 35 U.S.C. § 102(e) as being anticipated by Johnston (US 6,023,932). It is respectfully submitted that this ground of rejection is in error and no response other than the statement to follow is deemed necessary.

As the Examiner likely is aware, the decision of the Supreme Court in *Alexander Milburn Company v. Davis – Bournonville Company*, 270 U.S. 390 (1926), is the genesis of the of so-called "secret prior art" rejection, and the grant of statutory permission to consider the written disclosure in an application of another as potential prior within the meaning of Section 102(e). Secret prior art in an application may be considered if it meets two criteria: first, a disclosure proposed to be considered potential prior art in an application pending on the effective

date of filing of the application under examination; and, second, the application actually issues as a patent or a Statutory Invention Registration (“SIR”) after the effective filing date.

The criteria are not met since the Johnston ‘932 patent was not pending on the effective date of filing of the application under examination. The Johnston ‘932 patent issued on February 15, 2000, some three plus months prior to the effective date of filing of the application on May 22, 2000.

While the Johnston ‘932 patent may be prior art under certain circumstances in rejecting claims of the application under examination, the Johnston ‘932 patent is considered not prior art under 35 U.S.C. §102(e).

The Examiner, however, supports the rejection of claims 1, 7 – 9 and 23 under 35 U.S.C. § 102(e) with reference to the Manual of Patent Examining Procedure (“MPEP”) § 2132.01 (Aug. 2001). The MPEP section states “...when the reference is a U. S. patent published within the year prior to the application filing date, a 35 U.S.C. 102(e) rejection should be made.”

Applicant submits that there is an error in the previous statement.

The American Inventors Protection Act of 1999, Pub. L. 106 – 113, 113 Stat. 1501 (1999) (“AIPA”) was enacted by the Congress on November 29, 2000 for purposes, among others, of amending 35 U.S.C. § 102(e). It is respectfully submitted, however, that the amendment did not address the basic concept of “secret prior art.” The amendment, rather, added to the section the possibility of the “secret prior art” coming to light before the grant of a patent under circumstances that the application is published.

Pre-AIPA prior art included potentially the disclosure in a patent application of another, pending on the date of filing the application under examination. If the application issued as a patent or SIR after the date of filing of the application under examination the disclosure became

prior art as of the date of its filing of the pending application. With enactment of the AIPA, certain U. S. patent application publications were added to the category of potential prior art under section 102(e) during post-AIPA examination.

Later, Congress enacted the Intellectual Property and High Technology Technical Amendments Act of 2002, Pub. L. 107 – 273 (2002) (“H. R. 2215”). H. R. 2215, as it pertains to the AIPA, it is believed, had the affect, only, of changing the dates upon which certain changes wrought by the AIPA became effective in order to eliminate some inconsistencies that were recognized in applying prior art under section 102(e). The inconsistencies arose because of the use of different criteria in examining applications. According to H. R. 2215, all applications undergoing examination, irrespective of their date of filing, are examined under post-AIPA examination procedure.

Actually, neither the AIPA nor H.R. 2215 has anything to do with the prosecution of this application. Applicant mentions the history, however, since it is considered clear that the statement in the MPEP to which the Examiner referred concerns procedures in examining applications and the manner of handling a rejection under section 102(e), utilizing post-AIPA examination procedures.

Applicant respectfully submits that MPEP § 2132.01 (Aug. 2001), having relevance to post-AIPA section 102(e) is in error and should read “...a U. S. patent [application] published within the year prior to the application filing date...”

Applicant’s position is based on the observation that the language in the section of the MPEP under consideration is unusual since typically when referring to a U. S. patent the wording normally seen is the patent was “granted” or the patent was “issued,” but not that the patent was “published.”

An article is “published” and a “publication” is the essence of the discussion in the first paragraph of MPEP § 2132.01. It is considered unlikely, when one considers the overall content of the first paragraph that the section of the MPEP would address the handling of a patent rather than a printed publication, both of which have independent standing in the considerations of novelty under any one of sections 102(a), 102(b), and 102(e).

Applicant respectfully submits that the position taken regarding a proper reading of MPEP § 2132.01 is the correct position since the AIPA, other than adding certain publications to the category of potential prior art for consideration in the examination process under 35 U.S.C. § as it existed for years, did nothing to change the basic requirements of what constitutes prior art within the meaning of Section 102(e).

Assuming, arguendo, that the Johnston ^{→ Patent} application was published within the criteria of MPEP § 2132.01, the publication still would not be prior art within the meaning of section 102(e) since the Johnston ‘932 patent issued before the effective date of filing of the application under examination on May 22, 2000.

Before turning to the other rejections of claims under 35 U.S.C. § 102(b) as anticipated by the prior art, and the rejections of claims under 35 U.S.C. § 103(a) as made obvious by the prior art, applicant points out that the only claims in the application under examination not allowed, objected to (with the comment that they would be allowed if rewritten in independent form to included the limitations of the base claim and all intervening claims), or canceled are claim 68, a new independent claim, and dependent claims 6, 7, 10, 15 through 18, 23 and 32.

More particularly, claim 58 was allowed in the Office communication to which this amendment is in response. Claim 11 is rewritten in independent form appearing as new claim 59. Claims 12 through 14, 19 through 22, 25 through 31, 49, 60 through 62 and 67 are

dependent on claim 59. Claim 46 is rewritten in independent form appearing as new claim 63. Claims 54 through 57 are dependent on claim 63. Claim 47 is rewritten in independent form appearing as new claim 64. Claim 51 is rewritten in independent form appearing as new claim 65. Claim 52 is dependent on claim 65. Claim 53 is rewritten in independent form appearing as new claim 66. Each of these claims now should be indicated as allowable.

Claims 1 through 5, 8, 9, 11, 24, 26, 27, 33 through 47, 50, 51 and 53 are authorized to be canceled.

Turning again to **“Claim Rejections – 35 U.S.C. § 102”**

Claims 1, 2, 5, 7 through 9 and 23 were rejected under 35 U.S.C. § 102(b) as being anticipated by Patz et al (US 5,800,490). In this rejection, the examiner indicated that the electronic device 85 attached to the wrap which, in turn, is adapted to be attached to the body of the user (see Figs. 1 and 3 – 11) is a Peltier device.

New independent claim 68 and dependent claims 7 and 23 are the only claims of those identified and rejected as anticipated by Patz et al that remain under examination. These claims will be considered in the following comments.

For the reasons to follow, it is respectfully submitted that each of those claims are patentable over the Patz et al disclosure, and favorable reconsideration of the rejection is requested.

Claim 68 recites an apparatus for providing therapeutic heating and cooling to a body surface by means of electronics including at least one temperature sensor, a control unit, and at least one TE device. The apparatus includes a wrap adapted to be secured to the body surface. Particularly, the wrap includes inner and outer lamina and a plurality of intermediate lamina each being substantially coextensive in area and formed of a material facilitating substantially an

encircling movement in securing the wrap around the body at a location to receive therapeutic treatment. The temperature sensor, TE device and control unit are supported by the wrap, and particularly by various lamina forming the laminated construction.

The Patz et al patent disclosure on the other hand describes a tubular member formed by inner and outer shells, each providing an opening into the interior from opposite ends. The openings are of different size to more closely accommodate, for example, the upper arm and forearm within respective openings.

The inner and outer shells are joined together by sewing a seam first longitudinally and then around the circumference of the openings. A plurality of cutout regions are provided in the tubular member through both the inner and outer shells and electrical devices, such as a Peltier device, cooling jack and other devices, may be received in individual ones of the cutouts. A mesh material is carried within and secured to the tubular member. The mesh material functions to create a pocket for an individual device when the device is located to and forced partially through a respective cutout in the tubular member. A plurality of strap members are provided to draw the tubular member into somewhat closer proximity with the body surface over which the tubular member is received.

While the heating and cooling device disclosed by Patz et al discloses a Peltier device, the structure otherwise is quite dissimilar from the apparatus disclosed and claimed in claim 68 and dependent claims 7 and 23. To this end, Patz et al neither disclose nor suggest a wrap of laminated form including an inner and outer lamina and a plurality of intermediate lamina for supporting various electrical devices, with each lamina being substantially coextensive in size and formed of a material facilitating substantially an encircling movement of all lamina when securing the wrap to the body of a patient receiving therapy.

It is respectfully submitted, based on the differences in construction and operation of the apparatus of the invention and the apparatus described by Patz et al, that claims 68, 7 and 23 are allowable.

Favorable reconsideration of the rejection of claims 68, 7 and 23 as anticipated Patz et al is requested, and applicant looks forward to an indication that claims 68, 7 and 23 are allowable as presently written.

Claims 33 and 36 through 38 were rejected under 35 U.S.C. § 102(b) as being anticipated by Nowak (US 3, 132,688). Each of claims 33 and 36 through 38 have been authorized canceled and no comment regarding the prima facie case of rejection of claims as anticipated by Nowak is deemed necessary.

Regarding “Claim Rejections – 35 U.S.C. § 103(a)”

Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Patz et al in view of Nowak. Claims 3 and 4 have been authorized canceled and no comment regarding the prima facie case of rejection of claims 3 and 4 as anticipated by Nowak is deemed necessary.

Claims 1 through 5, 7 through 10, 23, 32, 33 and 36 through 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Chapman (US 3,648,469) in view of Gray (US 6,024,762), Nowak and further in view of Patz et al. Of the aforementioned claims only claims 7, 10, 23 and 32 remain under examination. Claims 1 through 5, 8, 9, 33 and 36 through 38 have been canceled.

In the rejection, the examiner asserts that Chapman discloses a flexible therapeutic heating pillow with a Peltier device therein and a control 17. The examiner next takes the position that the claims differ from the Chapman disclosure in reciting that the heating pillow is adapted to be secured to a body surface. The examiner also takes the position that the claims

differ from the Chapman disclosure in reciting that the control unit is responsive to sensed temperature from a temperature sensor. Further, the examiner takes the position that the claims differ from the Chapman disclosure in calling for the control unit to be mounted on the wrap.

While it may be conventional and well known in the art to secure the pillow disclosed by Chapman to a body surface, as evidenced by the Gray disclosure, and to sense temperature by a temperature sensor, such as the temperature sensor disclosed by Nowak thereby to provide a control input to the control disclosed by Chapman, as well as to mount the control disclosed by Chapman according to the teaching in the Patz et al disclosure, modified Chapman still differs substantially from the subject matter of claim 68 and dependent claims 7, 10, 23 and 32.

To this end, neither Chapman nor the Gray, Nowak and Patz et al disclosures either teach or suggest the form of the wrap of the apparatus of the invention as discussed above in connection with the discussion directed to the Nowak and Patz et al disclosures.

Neither Chapman nor Gray add to the deficiencies of Nowak and Patz et al regarding the construction of the wrap of the apparatus of the invention. Turning to Chapman, it merely discloses a pillow with internal heating/cooling. In operation, one surface of the pillow is heated and the other surface is cooled. Gray discloses a pillow of somewhat similar construction. Neither reference, however, discloses a wrap in the form of a laminate including inner and outer lamina with a plurality of lamina therebetween, with each lamina being substantially coextensive in size and formed of a material permitting the lamina to encircle the surface of the body to which the wrap is secured.

Favorable reconsideration of the rejection of claims 68, 7, 10, 23 and 32 is respectfully requested, and early favorable word regarding the allowance of these claims is requested.

Claims 6, 15 and 17 are rejected under 35 U.S.C § 103(a) as being unpatentable over Johnston or Patz et al in view of Nishida et al (US 4,633,062). The same claims are also rejected under the same grounds over Chapman in view of Gray, Nowak, Patz et al and further in view of Nishida et al.

Turning to each rejection, the examiner indicated that the claims differ from the prior art in calling for a pressure sensor mounted to the wrap to control a control unit when the pressure sensor is activated. After stating the issue, the examiner indicated that the use of pressure sensors as human body detection means in flexible heated wraps is conventional and well known in the art as evidenced by Nishida et al.

Assuming that Nishida et al discloses the use of a pressure sensor as the examiner suggests, the examiner does not explain how the combination of references is to be utilized in demonstrating obviousness. Nevertheless, it is apparent that Nishida et al, just as is the case with the references to Johnston, Patz et al, Chapman, Gray and Nowak, fails to disclose the wrap as recited and discussed throughout this amendment both in structure and the manner of operation is supporting the wrap around a body surface.

Favorable reconsideration of these grounds of rejection is requested.

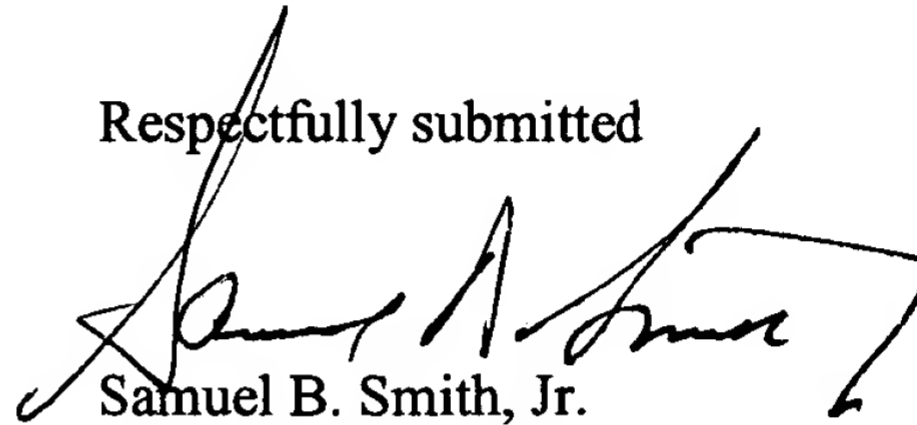
Finally, claim 16 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnston or Patz et al in view of James (US 5,601,618). The claims are also rejected on the same grounds as unpatentable over Chapman in view of Gray, Nowak, Patz et al and further in view of James.

In these rejections, the examiner took the position that the claims differ from the prior art in calling for at least one electrode to transmit a pulse to the body surface. Whether or not it is conventional and well-known in the art as evidenced by James to deliver electrical pulses to the

body, the fact remains that neither James nor Johnston and Patz et al, on the one hand, and Chapman, Gray, Nowak and Patz et al, on the other hand, disclose the structure and material of the wrap as discussed heretofore, and as disclosed in the subject matter of the invention recited in claims 68, 16 and 18.

Favorable reconsideration of all grounds of rejection and all grounds of objection are respectfully requested.

Respectfully submitted

A handwritten signature in black ink, appearing to read 'Samuel B. Smith, Jr.', with a stylized, sweeping flourish extending from the end of the signature.

Samuel B. Smith, Jr.
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CLAIMS AMENDED, ILLUSTRATING THE SEVERAL CHANGES FOR COMPARISON

6. (Amended) The apparatus of claim [1] 68, further comprising a pressure sensor mounted to said wrap, said pressure sensor adapted to turn ON said control unit when said pressure sensor is activated.

7. (Amended) The apparatus of claim [1] 68, [wherein said wrap includes] further including a strap, said strap mounted on the outer surface of said outer layer and adapted to attach said wrap to [the] said body surface.

10. (Amended) The apparatus of claim 8, wherein said wrap further includes a first elastic layer positioned between said [upper] outer layer and each said [at least one] TE device, and a second elastic layer [and said at least one TE device, and a second elastic layer] positioned between each said [at least one] TE device and said inner layer.

12. (Amended) The apparatus of claim [11] 59, wherein said wrap further includes [a] first [insulative layer positioned between said first conductive layer and said at least one TE device,] and [a] second [insulative layer] insulate layers [and said at least one TE device, and a second conductive layer], said insulate layers positioned between said [at least one TE and said] first and second conductive layers, on opposite sides of and contacting each said [least one] TE device [to said first and second conductive layers].

13. (Amended) The apparatus of claim 12, wherein said wrap further includes a wiring/tubing layer positioned between said first [insulative layer and said at least one TE device,] and [a] second [insulative layer positioned between said at least one TE device and said layer] insulate layers.

17. (Amended) The apparatus of claim [1] 68, further comprising at least one pressure sensor mounted to said wrap [from] for receipt of information from said control unit.

18. (Amended) The apparatus of claim [1] 68, further comprising at least one electrode mounted to said wrap for receipt of information from said control unit and for transmission of an electric pulse to [the] said body surface.

19. (Amended) The apparatus of claim 12, [wherein] further comprising first cavity means for receipt of fluid located between and formed by said second insulate layer and said wiring/tubing layer [define therebetween at least one cavity for receipt of fluid].

20. (Amended) The apparatus of claim 12, [wherein] further comprising second cavity means for receipt of fluid located between and formed by said first insulate layer and said wiring/tubing [define therebetween at least one cavity for receipt of fluid].

21. (Amended) The apparatus of claim 19, wherein said [at least one] second cavity means comprises two smaller cavities [connected by], and a fluid passage connecting said smaller cavities.

22. (Amended) The apparatus of claim 20, wherein said [at least one] first cavity means comprises two smaller cavities [connected by], and a fluid passage connecting said smaller cavities.

23. (Amended) The apparatus of claim [1] 68, wherein each said [at least one] TE device comprises a Peltier device.

25. (Amended) The apparatus of claim [24] 60, further comprising at least one pressure sensor disposed on said [lower] outer surface of said [lower] inner layer.

28. (Amended) The apparatus of claim [27] 62, further comprising at least one pressure sensor disposed on the [lower] inner surface of said [lower] inner layer.

29. (Amended) The apparatus of claim [27] 62, further comprising at least one electrode disposed on the [lower] inner surface of said [lower] inner layer.

30. (Amended) The apparatus of claim [27] 62, further comprising at least one pouch disposed on the [lower] inner surface of said [lower] inner layer for placement of [electrodes] at least one electrode.

31. (Amended) The apparatus of claim [27] 62, further comprising a template for the location of [electrode(s)] each said electrode on [the] said body [of user] surface, and the appropriate pouch disposed on the [lower] inner surface of said [lower] inner layer [by a clinician].

32. (Amended) The apparatus of claim [1] 68, wherein said control unit comprises;

a power source;

a controller;

a first switch[,] responsive to [the] said actual temperature detected by each said [at least one] temperature sensor[,] that turns [off] OFF said power source when [the] said actual temperature is above a maximum temperature or below a minimum temperature; [and]

a second switch electrically communicating with each said [at least one] TE device and adapted to operate each said TE device to deliver heating or cooling; and

each said [at least one] TE device connected to receive a signal from said controller corresponding to [the] said desired temperature and to deliver [at least] one of heating and cooling to [the] said body surface in response to [the] said desired temperature.

48. (Amended) The device of claim [42] 60, further comprising an electrical stimulation unit, said electrical stimulation unit connected to said microprocessor[,] for delivery of an electrical pulse to [the] said body surface.

52. (Amended) The device of claim [51] 65, wherein said iontophoresis unit comprises a medication interface connected to said microprocessor, a medication controller unit connected to

said medication interface, a medication dispenser connected to [the] said medication controller, and at least one special electrode connected to said medication dispenser to deliver [the] said medication to [the] said body surface.

54. (Amended) The device of claim [46] 63, further comprising a data link unit[,] connected to said microprocessor[,] for transfer of information to and from [the] said microprocessor.